



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0255; FRL-9917-56]

Metrafenone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metrafenone in or on multiple commodities that are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0255, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDNRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0255 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0255, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 25, 2014 (79 FR 10458) (FRL-9906-77), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8211) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.624 be amended by establishing tolerances for residues of the fungicide metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, in or on apricot at 0.7 parts per million (ppm); cherry subgroup 12-12A at 2.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 4.5 ppm; hop, dried cones at 70 ppm; peach subgroup 12-12B at 0.7 ppm; and vegetable, cucurbit, group 9 at 0.5 ppm. The petition also requested to remove the existing tolerance in 40 CFR 180.624 for grape at 4.5 ppm upon establishment of the proposed tolerances. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Also, in the **Federal Register** of May 23, 2014 (79 FR 29729) (FRL-9910-29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8187) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, requesting to establish a tolerance in 40 CFR part 180 for residues of metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone in or on vegetables, fruiting, group 8-10 at 1.0 ppm. That document referenced a summary of the petition prepared by BASF, which is available in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing that was the same as the one submitted for petition 3E8211. EPA's response to this comment is discussed in Unit IV.C.

Lastly, in the **Federal Register** of September 12, 2013 (78 FR 56185) (FRL-9399-7), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the

filing of a pesticide petition (PP 3F8163) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, requesting to establish a tolerance in 40 CFR part 180 for residues of the fungicide metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, in or on fruits, pome group 11-10 at 1.5 ppm. That document referenced a summary of the petition prepared by BASF, which is available in the docket, <http://www.regulations.gov>. No comments were received on the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the level at which some of the tolerances are being established and revised some of the commodity definitions for the requested crops. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for metrafenone including exposure resulting from the

tolerances established by this action. EPA's assessment of exposures and risks associated with metrafenone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The liver is the primary target organ for metrafenone in mice, rabbits and rats. Effects on the liver were seen in multiple studies throughout the database, including subchronic rat studies, the rabbit developmental toxicity study, and chronic studies in mice and rats. Liver effects observed in subchronic studies included increased liver weights, periportal cytoplasmic vacuolation, increased cholesterol, and hepatocellular hypertrophy. Liver effects observed in chronic studies included those from the subchronic studies as well as increased serum gamma glutamyl transferase, eosinophilic alterations, necrosis, polyploid hepatocytes, bile duct hyperplasia, liver masses, and hepatocellular adenomas. The additional effects in the chronic studies indicate a progression of toxicity with time. The effects on the liver are consistent with the results of the absorption, distribution, metabolism, and excretion (ADME) studies indicating that the highest tissue concentrations of metrafenone were found in the liver and gastrointestinal tract and that bile is the primary route of excretion.

Additionally, nephrotoxicity was observed following chronic exposure to metrafenone in mice and rats. The kidney effects observed in the chronic studies included subacute/chronic interstitial inflammation and chronic/progressive nephropathy, cysts, brown pigment in renal cells, increased urinary volume, and increased urinary protein.

In a 28-day dermal toxicity study in rats, there were no dermal or systemic effects observed up to the highest dose tested of 1,000 mg/kg/day, the limit dose. In a 28-day immunotoxicity study in female rats, no effect on the immune system was observed up to the highest dose tested of 1,000 mg/kg/day, the limit dose. This is consistent with the rest of the database where no effects on the immune system were observed in any study.

There was no evidence of qualitative or quantitative susceptibility in the developmental and reproduction toxicity studies. In the developmental rat study, no effects were observed in dams or fetuses up to the limit dose of 1,000 mg/kg/day. In the rabbit study, liver toxicity (increased liver weights, hypertrophy, and hepatocyte vacuolation) was observed in the dams but no developmental effects were observed up to the limit dose of 1,000 mg/kg/day.

In the rat reproduction toxicity study, there was no evidence of reproductive toxicity. Effects in the offspring (decreased pup weight) occurred at doses similar to those that cause toxicity in the parental animals (decreased body weight).

The required battery of mutagenicity studies was submitted, including bacterial reverse mutation assay, mammalian cell mutation (CHO cells), *in vitro* chromosome aberration (CHO cells), micronucleus assay and unscheduled DNA synthesis in mammalian cells in culture. There is no evidence that metrafenone is genotoxic.

In the mouse carcinogenicity study, liver tumors (increased incidence of hepatocellular adenomas and adenomas plus carcinomas) were observed in male mice at the highest dose of 1,109 mg/kg/day. In the rat chronic/carcinogenicity study, there was an increased incidence in hepatocellular adenomas in females at the high dose of 1,419 mg/kg/day. However, the tumors in the rat females were not considered in the weight-of-evidence finding because they were associated with excessive toxicity to the females, leading to a reduction of the dose during the study. The registrant submitted mechanistic studies to support a mode of action (MOA) for the

liver tumors, but the studies were conducted in rats. Although the MOA was considered plausible, the Agency concluded the data on rats could not be used to support a MOA finding in mice. The Agency concluded that quantification of cancer risk using a non-linear approach would adequately account for all chronic toxicity (including carcinogenicity) that could result from exposure to metrafenone. The use of the chronic point of departure is protective based on the following reasons:

- A treatment-related increase in benign liver tumors was seen only in male CD-1 mice at doses that were adequate to assess the carcinogenicity.
- The liver tumors were observed at doses significantly higher (44x) than those currently used for risk assessment.
- No treatment-related tumors were seen in female mice.
- No treatment-related tumors were seen in male rats and liver tumors in female rats were seen only at the Limit Dose which was excessively toxic to females; no tumors were seen at the next dose of 5,000 ppm, which was considered adequate to assess carcinogenicity.
- There is no mutagenicity concern for metrafenone

Specific information on the studies received and the nature of the adverse effects caused by metrafenone as well the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled “*Metrafenone. Human Health Risk Assessment for the Section 3 Registration on: Apricot, Cherry (Crop Subgroup 12-12A); Fruiting Vegetables (Crop Group 8-10); Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit (Crop Subgroup 13-07F); Hops, Dried Cones; Peach (Crop Subgroup 12-12B), Pome Fruit (Crop Group 11-10), and*

Vegetable, Cucurbit (Crop Group 9); Evaluation of Conditional Data.” on pages 31-40 in docket ID number EPA-HQ-OPP-2013-0255.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for metrafenone used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Metrafenone for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects

Acute Dietary (General population, including Infants and Children and females 13-49)	No appropriate single dose endpoint was identified in the submitted toxicity database.		
Chronic dietary (All populations)	NOAEL= 24.9 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.249 mg/kg/day cPAD = 0.249 mg/kg/day	Chronic /Carcinogenicity – rat LOAEL (mg/kg/day) = 260, based on hepatotoxicity and nephrotoxicity in both sexes
Cancer (Oral, dermal, inhalation)	Quantification of cancer risk using a cancer potency factor is not required; the chronic reference dose is protective of potential cancer risk.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metrafenone, EPA considered exposure under the petitioned-for tolerances as well as all existing metrafenone tolerances in 40 CFR 180.624. EPA assessed dietary exposures from metrafenone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for metrafenone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA).

As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance level residues (adjusted to account for additional residues of concern).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that the use of the chronic point of departure is appropriate for assessing cancer risk **to metrafenone**. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for metrafenone. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for metrafenone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of metrafenone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of total metrafenone for chronic exposures are estimated to be 14.52 parts per billion (ppb) for surface water and 12.3 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 14.52 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Metrafenone is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found metrafenone to share a common mechanism of toxicity with any other substances, and metrafenone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that metrafenone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of qualitative or quantitative susceptibility in the developmental and reproduction toxicity studies. In the developmental rat study, no effects were observed in dams or fetuses up to the limit dose of 1,000 mg/kg/day. In the rabbit study, liver toxicity (increased liver weights, hypertrophy, and hepatocyte vacuolation) was observed in the dams but no developmental effects were observed up to the limit dose of 1,000 mg/kg/day.

In the rat reproduction toxicity study, there was no evidence of reproductive toxicity. Effects in the offspring (decreased pup weight) occurred at doses similar to those which cause toxicity in the parental animals (decreased body weight).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for metrafenone is complete.
- ii. There is no indication that metrafenone is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that metrafenone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues (adjusted to account for additional residues of concern). EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to metrafenone in drinking water. These assessments will not underestimate the exposure and risks posed by metrafenone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, metrafenone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to metrafenone from food and water will utilize 16% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for metrafenone.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short- and intermediate-term adverse effect was identified; however, metrafenone is not registered for any use patterns that would result in short- and/or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- and intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-

and intermediate-term risk), no further assessment of short- and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for metrafenone.

4. *Aggregate cancer risk for U.S. population.* EPA considers the chronic aggregate risk assessment to be protective of any aggregate cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to metrafenone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method FAMS 105-01, a gas chromatography method with electron capture or mass spectrometry detector) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the

United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for metrafenone.

C. Response to Comments

EPA received a comment to the Notice of Filing that made a request to reconsider “loosening tolerances” for several pesticide petitions, including for metrafenone. The commenter points to an American Academy of Pediatrics Policy statement regarding pesticide exposure in children, a Centers for Disease Control and Prevention report on human exposure to environmental chemicals, and a President’s Cancer Panel regarding reducing environmental cancer risks in supporting the request to reconsider the tolerance amendments proposed for metrafenone.

The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food, or that pesticide tolerances should be “significantly tightened” as the commenter notes. However, the existing legal framework provided by section 408 of FFDCA states that tolerances may be set when EPA determines that aggregate exposure to that pesticide is safe, i.e., that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. When making this determination, EPA considers the toxicity, including any potential carcinogenicity, of the pesticide and all anticipated dietary exposures and all other exposures for which there is reliable information. EPA also gives special consideration to the potential susceptibility and exposures of infants and children to the pesticide chemical residue when making this determination. For metrafenone, the Agency has considered all the available data, including all available data concerning the potential for carcinogenicity of metrafenone and its

metabolites, and concluded after conducting a risk assessment, that there is a reasonable certainty that no harm will result from aggregate human exposure to metrafenone and that, accordingly, the metrafenone tolerances are safe.

A second comment was received stating that “I do not support use of this toxic chemical anywhere on earth.” Additionally, the commenter wrote that “any chemical should be fully investigated for its harm before being released for use.” As noted above, the Agency understands the commenter's concerns and recognizes that some individuals believe that pesticide chemicals should not be permitted in our food or for use anywhere. As to being investigated for its harm, metrafenone has an extensive toxicity database that has been fully evaluated by EPA. As noted above, the Agency has considered all the available data and concluded that there is a reasonable certainty that no harm will result from aggregate human exposure to metrafenone and that, accordingly, the metrafenone tolerances are safe.

D. Revisions to Petitioned-For Tolerances

EPA has modified some of the tolerances that were originally requested in the petition. Instead of the requested tolerance for cucurbit vegetables at 0.5 ppm, EPA is establishing the tolerance at 0.50 ppm, in order to avoid the situation where a field sample containing residues significantly above the tolerance (0.54 ppm, for example) would be considered non-violative. For the same reason, EPA is revising the requested tolerances of 0.7 ppm in the peach subgroup (12-12B) and in apricot to 0.70 ppm.

EPA has also revised the tolerance for residues of metrafenone in fruiting vegetables from 1.0 ppm to 0.90 ppm based on available residue data and using the Organisation for Economic Cooperation and Development/Maximum Residue Limit (OECD MRL) tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of metrafenone, including its metabolites and degradates, in or on apricot at 0.70 ppm; cherry subgroup 12-12A at 2.0 ppm; fruit, pome, group 11-10 at 1.5 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 4.5 ppm; hop, dried cones at 70 ppm; peach subgroup 12-12B at 0.70 ppm; vegetable, cucurbit, group 9 at 0.50 ppm; and vegetable, fruiting, group 8-10 at 0.90 ppm.

In addition, the existing tolerance on grapes is being removed as unnecessary since a tolerance is being set for crop subgroup 13-07F, which includes grape. The tolerance for raisins is still required and is not being deleted.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 10, 2014.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.624 is amended by removing the entry for “grape”, and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.624 Metrafenone; tolerances for residues.

(a) * * *

Commodity	Parts per million
Apricot	0.70
Cherry subgroup 12-12A	2.0
Fruit, pome, group 11-10	1.5
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	4.5
* * * *	* * *
Hop, dried cones	70
Peach subgroup 12-12B	0.70
Vegetable, cucurbit, group 9	0.50
Vegetable, fruiting, group 8-10	0.90

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